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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,663	02/06/2002	Chuan Li		9010

Chuan Li
Apt. 158
7908 Avenida Navidad
San Diego, CA 92122

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EXAMINER

WALLENHORST, MAUREEN

ART UNIT	PAPER NUMBER
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1743

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/068,663	Applicant(s) LI, CHUAN	
	Examiner Maureen M. Wallenhorst	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on January 8, 2007(RCE and February 9, 2007).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 48-55 is/are allowed.
- 6) ☒ Claim(s) 39-47, 56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 9, 2007 has been entered.

2. Claim 56 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 56, the phrase "the detection assay in making the protein standard" lacks antecedent basis and is indefinite since independent claim 48, from which claim 56 depends, does not positively recite any steps used to make the protein standard. Only a single detection assay is positively recited in claim 48, and that detection assay is used to detect the polypeptides in both the protein standard and in the protein sample being analyzed. There is nothing contained in independent claim 48 concerning making a protein standard.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 39-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizutani (US Patent no. 3,880,814).

Mizutani teaches of a composition or sample solution comprising at least three polypeptides of different known size and of different known amounts. The sample solution comprises 15 mg of the polypeptide conalbumin having a molecular weight or size of 87,000, 4 mg of ovalbumin having a molecular weight or size of 46,000, and 7 mg of lysozyme having a molecular weight or size of 14,600. See lines 6-13 in column 4 of Mizutani. The three polypeptides in the composition taught by Mizutani are the same polypeptides as taught in Example 1 on page 11 of the instant specification, and therefore, the size of the polypeptides disclosed by Mizutani would inherently cover a range that is separable by polyacrylamide gel electrophoresis, and the amounts of the polypeptides taught by Mizutani would inherently cover a range that is detectable by a given protein detection assay.

Mizutani fails to teach that the polypeptides conalbumin, ovalbumin and lysozyme are present within a kit, and fail to teach that in preparing the solution containing the three polypeptides, the amounts of the polypeptides are estimated using a detection assay with different amounts of a standard protein such as BSA. It would have been obvious to one of ordinary skill in the art at the time of the instant invention to incorporate the polypeptides in the solution taught by Mizutani into a kit so as to have all of the polypeptides present in a single container in the correct amount in order to facilitate the quick and easy performance of the

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method taught by Mizutani. It also would have been obvious to one of ordinary skill in the art at the time of the instant invention to estimate the recited amounts of the polypeptides taught by Mizutani (15 mg conalbumin, 4 mg ovalbumin and 7 mg lysozyme) using a detection assay with different amounts of a standard protein such as BSA since it is common knowledge in the art of protein assays to use a standard such as BSA in different known amounts in order to determine the amounts of polypeptides in an unknown sample, and to express the amounts of the polypeptides as equivalent amounts of the standard protein, as evidenced by Applicant's own admission in the response received on February 15, 2006.

6. Claims 48-55 are allowable over the prior art of record since none of the prior art of record teaches or fairly suggests a method for estimating both the size and amount of a polypeptide in a protein sample by electrophoresing simultaneously in separate lanes on a gel the protein sample and a protein standard containing at least three different polypeptides therein having different sizes from one another and being present in different amounts from one another, wherein the amounts of the polypeptides in the standard are expressed as an equivalent amount of a standard protein, detecting the polypeptides on the gel with a detection assay to obtain the relative positions and detection intensities of the polypeptides, comparing the relative positions of the polypeptides of the protein standard with the relative position of the polypeptide in the protein sample to estimate its size, and comparing the relative detecting intensity of the polypeptides of the protein standard with the relative detecting intensity of the polypeptide in the protein sample to estimate its amount.

7. Applicant's arguments filed February 9, 2007 have been fully considered but they are not persuasive.

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Applicant argues the previous rejections of the claims made in the Office action mailed on October 10, 2006 under 35 USC 103 as being obvious in view of Mizutani by stating that Mizutani fails to teach of using the polypeptides taught therein together as a protein standard on a gel in order to determine the size and quantity of a protein simultaneously since the staining intensities of the polypeptides do not reflect their quantities.

In response to Applicant's arguments, it is noted that Applicant's arguments are all directed to the method of use or intended use of the protein standard. This method of use, as recited in instant claims 48-55, has been indicated to be allowable over the prior art of record since Applicant's new principles of operation, as outlined in the response received on July 20, 2006, are persuasive regarding this method. However, Applicant's arguments are not persuasive for claims 39-47 since claim 39 is directed simply to a product/composition containing three different size polypeptides in each of three different amounts. The composition as taught in lines 6-13 of column 4 in Mizutani is the same exact product as recited in claim 39. The fact that a composition is intended for a new and unobvious use does not render the composition itself patentable. See *In re Pearson*, 181 USPQ 641 (CCPA 1974). In addition, claim 44 is directed to a method of preparing such a product by combining three different size polypeptides in three different amounts, which is also what Mizutani teaches. It would have been obvious to one of ordinary skill in the art to determine the amounts of each of the polypeptides in the product taught by Mizutani with a detection assay by comparing the relative staining intensities of the polypeptides on a gel with the relative staining intensities of different amounts of known proteins such as BSA or lysozyme since it is common knowledge in the art of protein assays to use a standard such as BSA in different known amounts in order to determine the amounts of

polypeptides in an unknown sample, and to express the amounts of the polypeptides as equivalent amounts of the standard protein, as evidenced by Applicant's own admission in the response received on February 15, 2006 and on pages 2-3 of the response received on February 9, 2007. All that independent claims 39 and 44 require is a mixture of three different polypeptides of different sizes and in different amounts. In addition, these claims require that the quantity of the polypeptides be estimated by comparison to a standard protein such as BSA or lysozyme in a detection assay (i.e. separating the polypeptides on a gel and staining with a dye such as Coomassie Blue). Applicant admits on pages 2-3 of the response received on February 9, 2007 that a protein detection assay using BSA as a standard material is most likely used to estimate the amounts of the polypeptides conalbumin, ovalbumin and lysozyme in the polypeptide mixture taught by Mizutani. Therefore, the reference to Mizutani meets all of the limitations recited in instant claims 39-47.

Applicant argues that since the method of using the protein standard of the instant invention is not obvious, then the claimed quantitative protein standard and method of making are also not obvious. In response to this argument, it is noted that claims directed to a product or composition are patentably distinct from claims directed to a method of using a product or composition. Product claims are patentably judged by what components they are comprised of, not based upon the methods the product can be used in or what the product is used for. Since the product taught by Mizutani contains all of the components recited in instant claims 39-43, the teaching of Mizutani renders obvious the product recited in claims 39-43 for the reasons set forth above in the rejection, even though the product of Mizutani is used in a different method than used by Applicant. Method of making claims are patentably judged by the specific steps used to

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formulate the composition, not upon other intended uses of the product. Since instant claims 44-47 only set forth steps of combining different polypeptides having different sizes and amounts from one another into a single composition, the steps taught by Mizutani render obvious these claims for the reasons set forth above in the rejection. Claims 44-47 do not contain any steps directed to using the protein standard to estimate the size and amount of polypeptides in an unknown protein sample.

Applicant also argues that the method of making and using the claimed quantitative protein standard are integral parts of the invention since the same staining assay has to be used in both detecting and estimating the quantity of each of the polypeptides in the protein standard as is used in detecting and estimating the quantity of polypeptides in an unknown protein sample by comparing the responses of the unknown sample with the protein standard. In response to this argument, it is noted that instant independent claims 39 and 44 do not recite that the staining assay used in detecting and estimating the quantity of each of the polypeptides in the protein standard has to be the same as the staining assay applied when using the protein standard to estimate the size and amount of polypeptides in an unknown protein sample. Claims 39 and 44 only recite a single detection assay used to detect and estimate the quantity of the polypeptides in the standard, and this detection assay could be any of the known protein assays used for many years (i.e. Coomassie Blue, Fast Green, silver, fluorescamine staining, etc.) to estimate the quantity of an unknown polypeptide. Claims 39 and 44 do not recite any other detection assays, or how the method of making the protein standard is integral or related to a method of using the protein standard by any common staining assay.

Applicant argues that the invention solves a long-felt, long-existing but unsolved need.

In response to this argument, it is noted that Applicant's argument with regards to solving a long-felt need is persuasive with regards to the method of using the protein standard to estimate both the size and amounts of polypeptides in a protein sample. However, since the reference to Mizutani teaches of a composition or product containing all of the sample polypeptides in different amounts and a method for making such a composition, the claims directed to the product and method for making (i.e. claims 39-47) do not solve any long-felt need since the product and method for making are already known.

Applicant also argues that no one has implemented the instant invention for over 30 years, thus rendering it non-obvious. This argument is persuasive for the method of using the protein standard, as indicated above in the reasons for allowance. However, this argument is not persuasive for the product claims 39-43 and method for making claims 44-47 since Mizutani teaches of such a product and a method for making.

In conclusion, claims 39-47 remain rejected as set forth above, and claims 48-55 are allowable over the prior art of record.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

September 19, 2006

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP 1700